

UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF
PENNSYLVANIA

CIVIL 2:18-CV-03916

CINDY MCGHEHEY,
Plaintiff,

v.

MERCK & CO., INC. and MERCK SHARP
& DOHME CORP.
Defendants.

MDL No. 2848
Civil Action No. 2:18-md-2848

PLAINTIFF CINDY MCGHEHEY FIRST AMENDED COMPLAINT

Plaintiff, by and through her counsel McNichol, Byrne & Matlawski, P.C. and
Vujasinovic and Beckcom, PLLC, alleges as follows:

PARTIES

1. Plaintiff Cindy McGhehey is a resident and citizen of McMinnville, Yamhill County, Oregon.
2. Merck & Co., Inc. is a New Jersey Corporation with its principle place of business at 1 Merck Drive, Whitehouse Station, NJ 08889. Merck & Co., Inc. may be served with process by serving its registered agent for service, CT Corporation System, 1635 Market St., Philadelphia, PA 19103.
3. Merck Sharp & Dohme Corp. is a subsidiary of Merck & Co, Inc. and also a

New Jersey Corporation. Merck Sharp & Dohme Corp. transacts business at 126 E Lincoln Ave, Rahway, NJ 07065. Merck Sharp & Dohme Corp. may be served with process by serving its registered agent for service, CT Corporation System, 1635 Market St., Philadelphia, PA 19103.

4. Merck & Co., Inc. and Merck Sharp & Dohme Corp. are collectively referred to as “Merck.”

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1391, because the amount in controversy as to Plaintiff exceeds \$75,000.00, exclusive of interest and costs, and because Defendants are all incorporated and have their principal places of business in states other than the states in which Plaintiff resides.

6. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because a substantial part of the events or omissions giving rise to Plaintiff’s claim occurred in this state. At all times relevant to this lawsuit, Merck was engaged in the business of designing, testing, manufacturing, labeling, licensing, marketing, distributing, promoting and/or selling, either directly or indirectly through third parties, the Zostavax vaccine within this District. Based upon information and belief, and at all times relevant hereto, Merck maintained a factory within this District, Merck West Point, located at 770 Sumneytown Pike, West Point, PA 19486 where Merck was engaged in the business of designing, testing, manufacturing, labeling, licensing, marketing, distributing, promoting and/or selling, either directly or indirectly through third parties, the Zostavax vaccine.

7. In addition, based upon information and belief, Merck is, and was at all times

relevant hereto,

- a. duly authorized to conduct business in Pennsylvania;
- b. regularly conducted and solicited business within Pennsylvania and continues to do so;
- c. does business in Pennsylvania, and at all times relevant hereto, has sold and distributed the Zostavax vaccine in Pennsylvania;
- d. derives substantial revenue from goods used or consumed in Pennsylvania;
- e. advertised its Zostavax vaccine to patients, doctors and hospitals in Pennsylvania and/or other medical facilities located in Pennsylvania;
- f. advertises or otherwise promotes its business in Pennsylvania; and
- g. reasonably expects to be subject to Pennsylvania product liability law.

NO FEDERAL PREEMPTION

8. The National Childhood Vaccine Injury Act of 1986 (“Vaccine Act”), 42 U.S.C. §§ 300aa-1 et seq. does not preempt Plaintiff from filing this Complaint. Pursuant to §11(c)(1)(A) of the Vaccine Act, the Vaccine Court has jurisdiction to only hear cases listed on the Vaccine Injury Table. The Zostavax vaccine is not a vaccine listed in the Vaccine Injury Table.

FACTS

9. At all times hereinafter mentioned, Merck designed, manufactured, licensed, labeled, tested, distributed, marketed and sold the Zostavax vaccine.

10. Zostavax was designed, developed, marketed, and sold with the intended purpose of preventing shingles, which is caused by the varicella zoster virus (VZV).

11. Varicella zoster is a virus that causes chickenpox.

12. Once the varicella zoster virus causes chickenpox, the virus remains inactive (dormant) in the nervous system for many years.

13. VZV can be reactivated due to factors, such as disease, stress, aging, and immune modulation caused by vaccination.

14. When reactivated, varicella zoster replicates in nerve cells and is carried down the nerve fibers to the area of skin served by the ganglion that harbored the dormant virus.

15. In May of 2006, the U.S. Food and Drug Administration (“FDA”) approved the Zostavax vaccine to be marketed and sold in the United States by Merck.

16. Zostavax was initially indicated for the “the prevention of herpes zoster (shingles) in individuals 60 years of age and older when administered as a single-dose.” FDA Approval Letter, May 25, 2006.

17. FDA approval was based in large part on the results of the Shingles Prevention Study (SPS) supported by Merck.

18. The results of the SPS were published in the New England Journal of Medicine on June 2, 2005. The paper was titled “A Vaccine to Prevent Herpes Zoster and Postherpetic Neuralgia in Older Adults”. N. Engl. J. Med. 2005; 352(22):2271-84.

- a. Shingles results from reactivation of latent varicella zoster virus (VZV), which is the virus that causes chickenpox. The incidence and severity of shingles increases as people age.

- b. As further described in this paper, “[t]he pain and discomfort associated with herpes zoster can be prolonged and disabling, diminishing the patient’s quality of life and ability to function to a degree comparable to that in diseases such as congestive heart failure, myocardial infarction, diabetes mellitus type 2, and major depression.” N. Engl. J. Med. 2005; 352(22) at 2272.
 - c. The Zostavax vaccine is essentially the same vaccine as that used for chickenpox, except significantly stronger.
 - d. Zostavax contains live VZV. The virulence of the virus is reduced or “attenuated”. Attenuated vaccines are designed to activate the immune system with the decreased risk of actually developing the disease.
 - e. Zostavax is developed from a live attenuated version of the Oka/Merck VZV vaccine strain.
 - f. One of the paper’s more significant findings was “[t]he greater number of early cases of herpes zoster in the placebo group, as compared with the vaccine group, and the fact that no vaccine virus DNA was detected, indicate that the vaccine did not cause or induce herpes zoster.”
19. A risk of using a live virus vaccine is that it is not weakened enough or “under-attenuated”.
20. Under-attenuated live virus creates an increased risk of developing the disease the vaccine was to prevent.
21. Under-attenuated live VZV has been shown to reactivate. Leggiadro, R. J. (2000).

Varicella Vaccination: Evidence for Frequent Reactivation of the Vaccine Strain in Healthy Children. *The Pediatric infectious disease journal*, 19(11), 1117–1118; Krause, P. R., & Klinman, D. M. (2000). *Nature Medicine*, 6(4), 451–454.

22. Once injected, attenuated live virus has been shown to recombine into more virulent strains causing disease.

23. Shingles is a reactivation of the latent VZV.

24. The approval granted by the FDA to allow the selling and marketing of this vaccine came with certain post-marketing commitments that Merck agreed to complete to, among other things, insure the safety of this vaccine. These included the following:

- a. A randomized, placebo-controlled safety study to assess the rates of serious adverse events in 6,000 people receiving the vaccine as compared to 6,000 who receive a placebo.
- b. An observational study using a health maintenance organization (HMO) and 20,000 vaccinated people to address safety issues in the course of clinical practice. This study is specifically to detect “potential safety signals following administration of Zostavax.” This study was to be submitted to the FDA by December 2008.

25. Since the publication of the SPS in the *New England Journal of Medicine*, there have been questions raised regarding the safety of Zostavax vaccine in scientific and medical journals.

26. Zostavax is a stronger, more potent version of Merck’s chickenpox vaccine,

Varivax.

27. Varivax contains a minimum of 1,350 PFU (plaque-forming units) of the virus while Zostavax contains a minimum of 19,400 PFU.

28. In the clinical studies evaluating Zostavax, more than 90% of the vaccinated subjects received 32,300 PFU.

29. Merck added several adverse reactions to its package insert/prescribing information since Varivax was approved.

- a. The biological system in which the most adverse reactions were added was the nervous system.
- b. Added reactions include: encephalitis, cerebrovascular accident, transverse myelitis, Guillain-Barré syndrome, Bell's palsy, ataxia, non-febrile seizures, aseptic meningitis, dizziness, and paresthesia.
- c. Acute Disseminated Encephalomyelitis is a type of encephalitis.

30. As of February 2014, the patient information sheet, label, and prescribing information distributed with the Zostavax vaccine contain no clear reference to the potential risk of viral infection.

31. Individuals with compromised immune systems should not receive a live virus vaccine because those individuals can develop the disease that the vaccine is designed to prevent.

32. The patient information sheet, as well as the label and prescribing information for Zostavax at all times relevant hereto, did not adequately, if at all, address the risk of viral infection. All that was addressed is the concern that a rash and itching might develop at the

injection site. This is despite the fact that shingles was a noted occurrence during clinical trials of the vaccine.

33. The prescribing information for Zostavax contains a warning that “[t]ransmission of vaccine virus may occur between vaccinees and susceptible contacts”.

- a. The risk of transmission of vaccine virus is due to active viral infection in individuals receiving the Zostavax vaccine.

34. The patient information sheet, as well as the label and prescribing information for Zostavax at all times relevant hereto, did not adequately, if at all, address the risk of viral infection or possible diseases of the nervous system. This is despite the fact that Varivax, a less potent vaccine, has added several neurological diseases and symptoms as adverse reactions to the Varivax vaccine.

35. Since Zostavax’s introduction in 2006, vaccine adverse event reports (VAERs) appeared in significant numbers addressing various adverse effects, including, but not limited to, viral infection resulting in disease of the central nervous system, including acute disseminated encephalomyelitis.

36. Other than postherpetic neuralgia, shingles can lead to other serious complications, such as scarring, bacterial superinfection, allodynia, cranial and motor neuron palsies, pneumonia, encephalitis, visual impairment, hearing loss, and death.

37. It follows that given the increased risk viral infection due to vaccination, such complications are also possible complications of Zostavax. It also follows that post-vaccination viral infection can cause significant issues in the nervous system due to the replication of the latent virus in the nervous system.

38. Despite this information and the potential correlation between being administered the Zostavax vaccine and within a relatively short period of time developing an infection, leading to the development of shingles or varicella-zoster virus pneumonia, Merck failed to properly address and provide this information both to the patient and the medical providers prescribing the vaccine.

39. In October 2017, the FDA approved Shingrix – an alternative shingles vaccine manufactured by GlaxoSmithKline. Shingrix was created by extracting a portion of the varicella zoster virus' DNA and adding it with an adjuvant, a substance that enhances the body's immune response to an antigen. When Shingrix enters the body, the portions of viral DNA induce an immune response that cannot directly infect the vaccinated human host nor activate dormant VZV virus. In direct contrast, Zostavax contain various mutated live strains of actual VZV virus which can directly infect the vaccinated human host and/or activate dormant VZV virus.

40. Shingrix was proven to be safe and effective to prevent shingles in over 90% of users in contrast to Zostavax's effectiveness rates that were as low as 18% in certain age groups. Shingrix was proven to stay effective in prevent shingles at least four years in contrast to Zostavax's effectiveness that waned over a five year period.

41. The safety, effectiveness, and the simple superiority of the design of Shingrix over Zostavax allowed the Center for Disease Control ("CDC") to make an unprecedented decision to recommend Shingrix over Zostavax to the general public after only a few days of Shingrix being approved by the FDA.

42. Upon information and belief, Merck possessed, or should have possessed, the

knowledge to create a Shingles vaccine similarly designed as Shingrix.

CASE-SPECIFIC FACTS

43. In or around August of 2016 Plaintiff saw commercials on TV that reasonably lead her to believe that Zostavax was a safe way to avoid getting shingles. It also informed her that because of her age she was in a high risk category which was an additional reason for getting the vaccination.

44. In or around August of 2016, Plaintiff received the Zostavax vaccine for its intended purpose: the prevention of shingles.

45. Plaintiff received the vaccine from the Bi-Mart Pharmacy at 13222 SW Peninsula Dr., Terrebonne, Oregon 97760. The injection was performed by Robin Adkins. Plaintiff saw a Zostavax advertisement in the pharmacy which informed her that the pharmacy had Zostavax and that it should be safe.¹

46. Paperwork attached to the pharmacy records specifically states that Zostavax is used for the prevention of shingles. The side effects listed are “pain where the shot was given,” “redness or swelling where the shot is given,” “irritation where the shot is given,” “itching,” and “headache.”² There was no warning of contracting shingles.

47. The attached vaccine information sheet states that “[s]hingles is a painful skin rash, often with blisters.”³ It also states “Its main symptom is pain, which can be quite severe. Other symptoms of shingles can include fever, headache, chills and upset stomach. Very rarely, a shingles infection can lead to pneumonia, hearing problems, blindness, brain

¹ Exhibit A, McGhehey Vaccination Records

² *Id.*

³ *Id.*

inflammation (encephalitis) or death.”⁴

48. The vaccine information fact she also stated that “A single dose of shingles vaccine is recommended for adults 60 years of age and older.”⁵

49. Nothing in the vaccine information fact she stated that she should not get the vaccine.⁶

50. The vaccine fact she states that “No serious problems have been identified with shingles vaccine.”⁷

51. Approximately two months later Plaintiff suffered from a severe case of shingles.

52. In or around October 2016, Plaintiff presented to her physician at the St. Charles Health System for this injury and was diagnosed with shingles.

53. As a direct and proximate result of Merck’s defective Zostavax vaccine, Plaintiff’s symptoms have resulted in physical limitations not present prior to using Merck’s product. Plaintiff also experiences mental and emotional distress due to resulting physical limitations and seriousness of his condition.

54. As a result of the manufacture, marketing, advertising, promotion, distribution and/or sale of Zostavax, Plaintiff sustained severe and permanent personal injuries. Further, as a tragic consequence of Merck’s wrongful conduct, Plaintiff suffered serious, progressive, permanent, and incurable injuries, as well as significant conscious pain and suffering, mental anguish, emotional distress, loss of enjoyment of life, physical impairment and injury.

⁴ *Id.*

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

55. Plaintiff has incurred and will continue to incur medical expenses and other economic harm as a direct result of use of Zostavax.

COUNT I: NEGLIGENCE

56. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

57. Merck had a duty to exercise reasonable care in the design, research, manufacture, marketing, testing, advertisement, supply, promotion, packaging, sale, and distribution of Zostavax including the duty to take all reasonable steps necessary to manufacture and sell a product that was not defective and unreasonably dangerous to consumers and users of the product.

58. Merck failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions, and distribution of Zostavax because Merck knew, or should have known, that its product caused viral infection, and was therefore not safe for administration to consumers.

59. Merck failed to exercise due care in the labeling of Zostavax and failed to issue to consumers and/or their healthcare providers adequate warnings as to the risk of serious bodily injury, including viral infection, resulting from its use.

60. Merck continued to manufacture and market its product despite the knowledge, whether direct or ascertained with reasonable care, that Zostavax posed a serious risk of bodily harm to consumers. This is especially true given its tenuous efficacy.

61. Merck knew, or should have known, that consumers, such as Plaintiff, would

foreseeably suffer injury as a result of Merck's failure to exercise ordinary care.

62. As a direct and proximate consequence of Merck's negligence, Plaintiff sustained serious personal injuries and related losses including, but not limited to, the following:

- a. Plaintiff required and will continue to require healthcare and services;
- b. Plaintiff incurred and will continue to incur medical and related expenses; and
- c. Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

WHEREFORE, Plaintiff demands judgment against Merck, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT II: STRICT LIABILITY: DESIGN AND MANUFACTURING DEFECT

63. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

64. Merck designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Zostavax vaccine.

65. The Zostavax vaccine was expected to, and did, reach the intended consumers, handlers, and persons coming in contact with the product with no substantial change in the

condition in which the product was designed, produced, manufactured, sold, distributed, labeled, and marketed by Merck.

66. The Zostavax vaccine was manufactured, designed, marketed, labeled and sold in a defective condition, for use by Plaintiff's physicians and/or healthcare providers, and all other consumers of the product, making the product unreasonably dangerous.

67. The Zostavax vaccine, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Merck was defective in design and formulation in that when it left the hands of the manufacturers, suppliers, and distributors, the foreseeable risks of harm caused by the product exceeded the claimed benefits of the product.

68. Merck's Zostavax vaccine, as designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Merck was defective in design and formulation, because when it left the hands of Merck, the product was unreasonably dangerous and was also more dangerous than expected by the ordinary consumer.

69. At all times relevant to this action, Merck knew and had reason to know that its Zostavax vaccine was inherently defective and unreasonably dangerous as designed, formulated, and manufactured by Merck, and when used and administered in the form manufactured and distributed by Merck, and in the manner instructed by Merck to be used and administered to Plaintiff and other consumers.

70. Plaintiff's physicians and/or healthcare providers used and administered the Zostavax vaccine for the purpose intended by Merck, and in a manner normally intended to be used and administered, namely for vaccination against shingles (herpes zoster). Merck had a duty to design, create, and manufacture products that were reasonably safe and not

unreasonably dangerous for their normal, common, and intended use. Merck's product was not reasonably fit, suitable, or safe for its anticipated use, and safer, reasonable alternative designs existed and could have been utilized. Reasonably prudent manufacturers would not have placed the product in the stream of commerce with knowledge of these design flaws.

71. Merck designed, developed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product that created an unreasonable risk of serious harm to the health, safety, and well-being of Plaintiff and other consumers. Merck is therefore strictly liable for the Plaintiff's injuries and damages sustained proximately caused by Plaintiff's use of the product.

72. Plaintiff could not, by the exercise of reasonable care, discover the defective condition of Merck's product and/or perceived its defective dangers prior to its administration by her physicians and/or healthcare providers.

73. Furthermore, Merck defectively manufactured the subject Zostavax vaccine such that it unreasonably increased the risk of contracting an infection from the vaccine.

74. Merck's defective Zostavax vaccine was a substantial, proximate, and contributing factor in causing Plaintiff's injuries.

75. As a proximate result of Merck's acts and omissions and Plaintiff's use of Merck's defective product, Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses to treat and care for her injuries described in this Complaint, including, but not limited to, the following:

- a. Plaintiff required and will continue to require healthcare and services;
- b. Plaintiff incurred and will continue to incur medical and related expenses; and

c. Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

WHEREFORE, Plaintiff demands judgment against Merck, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT III: FAILURE TO WARN

76. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

77. Merck designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Zostavax vaccine.

78. The Zostavax vaccine was expected to, and did, reach the intended consumers, handlers, and persons coming in contact with the product with no substantial change in the condition in which the product was designed, produced, manufactured, sold, distributed, labeled, and marketed by Merck.

79. The Zostavax vaccine was manufactured, designed, marketed, labeled and sold in a defective condition, for use by Plaintiff's physicians and/or healthcare providers and all other consumers of the product, making the product unreasonably dangerous.

80. Merck researched, developed, designed, tested, manufactured, inspected,

labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce its Zostavax vaccine and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of its product.

81. Merck's Zostavax vaccine, as designed, researched, developed, manufactured, tested, advertised, promoted, marketed, sold, labeled, and distributed by Merck, was defective due to the product's inadequate warnings and instructions. Merck knew, or should have known, and adequately warned that its product created a risk of serious and dangerous side effects, including but not limited to, viral infection resulting in shingles, postherpetic neuralgia, or other diseases of the nervous system.

82. The product was under the exclusive control of Merck and was unaccompanied by appropriate and adequate warnings regarding the risk of severe and permanent injuries associated with its use, including, but not limited to, the risk of developing a disease in the nervous system due to viral infection. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer.

83. Notwithstanding Merck's knowledge of the defective condition of its product, Merck failed to adequately warn the medical community and consumers of the product, including Plaintiff and Plaintiff's healthcare providers, of the dangers and risk of harm associated with the use and administration of its Zostavax vaccine.

84. Merck downplayed the serious and dangerous side effects of its product to encourage sales of the product; consequently, Merck placed its profits above its customers' safety.

85. The product was defective when it left the possession of Merck in that it contained insufficient warnings to alert Plaintiff and/or her healthcare providers to the dangerous risks and reactions associated with it, including possible viral infection of the nervous system or another disease of the nervous system.

86. Even though Merck knew or should have known of the risks and reactions associated with their product, it still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

87. Plaintiff used Merck's Zostavax vaccine as intended or in a reasonably foreseeable manner.

88. Merck, as a manufacturer of pharmaceutical products, is held to the level of knowledge of an expert in the field and, further, Merck had knowledge of the dangerous risks and side effects of its product.

89. Plaintiff did not have the same knowledge as Merck and no adequate warning was communicated to her physician(s) and/or healthcare providers.

90. Merck had a continuing duty to warn consumers of its Zostavax vaccine, including Plaintiff, of the dangers associated with its product, and by negligently and/or wantonly failing to adequately warn of the dangers of the use of its product, Merck breached its duty.

91. Although Merck knew, or should have known, of the defective nature of its Zostavax vaccine, it continued to design, manufacture, market, and sell its product without providing adequate warnings and instructions concerning the use of its product so as to maximize sales and profits at the expense of the public health and safety, in knowing,

conscious, and deliberate disregard of the foreseeable harm caused by its Zostavax vaccine.

92. As a direct and proximate result of Merck's failure to adequately warn or other acts and omissions of Merck described herein, Plaintiff was caused to suffer severe and permanent injuries, pain, and mental anguish, including diminished enjoyment of life.

93. Merck's failure to warn extended beyond the product's label and into other media available to Merck, including but not limited to advertisements, person-to-person sales calls, medical journal articles, and medical conference presentations.

94. The Zostavax vaccine, upon information and belief, as manufactured and supplied by Merck, was further defective due to inadequate post-market warnings or instructions because after Merck knew, or should have known, of the risk of serious bodily harm from the administration of its Zostavax vaccine, including, but not limited to, possible viral infection, Merck failed to provide adequate warnings to consumers and/or their healthcare providers about the product, knowing the product could cause serious injury.

95. The Zostavax vaccine, upon information and belief, as manufactured and supplied by Merck, was defective due to inadequate post-market warnings or instructions when it left Merck's control.

96. As a proximate result of Merck's acts and omissions and Plaintiff's use of Merck's defective product, Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses as set forth in this Complaint, including, but not limited to, the following:

- a. Plaintiff required and will continue to require healthcare and services;
- b. Plaintiff incurred and will continue to incur medical and related expenses; and

c. Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, and other losses and damages.

WHEREFORE, Plaintiff demands judgment against Merck, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT IV: BREACH OF EXPRESS WARRANTY

97. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

98. Merck, through its officers, directors, agents, representatives, and written literature and packaging, and written and media advertisements, expressly warranted that its Zostavax vaccine was safe and effective and fit for use by consumers, was of merchantable quality, did not create the risk of or produce dangerous side effects, including, but not limited to, viral infection, and was adequately tested and fit for its intended use.

a. Specifically, Merck stated that "ZOSTAVAX is a vaccine that is used for adults 60 years of age or older to prevent shingles (also known as zoster)."

b. Merck also stated that "ZOSTAVAX works by helping your immune system protect you from getting shingles."

c. Merck, in the SPS paper, stated that "...the vaccine did not cause or induce

herpes zoster.”

99. At the time of making such express warranties, Merck knew and/or should have known that its Zostavax vaccine did not conform to the express warranties and representations and that, in fact, its product was not safe and had numerous serious side effects, including the possibility of viral infection, of which Merck had full knowledge and did not accurately or adequately warn.

100. The Zostavax vaccine manufactured and sold by Merck did not conform to these representations because it caused serious injury, including diseases of the nervous system and/or viral infection, to consumers such as Plaintiff, when used in routinely administered dosages.

101. Merck breached its express warranties because its product was and is defective for its intended purpose.

102. Plaintiff, through Plaintiff’s healthcare providers, did rely on Merck’s express warranties regarding the safety and efficacy of their product in purchasing and injecting the product.

103. Members of the medical community, including physicians and other healthcare professionals, relied upon Merck’s representations and express warranties in connection with the use recommendation, description, and dispensing of Merck’s Zostavax vaccine.

104. As a foreseeable, direct, and proximate result of the breach of the express warranties, Plaintiff suffered severe and permanent personal injuries, harm, and economic loss.

WHEREFORE, Plaintiff demands judgment against Merck, and requests

compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT V: BREACH OF IMPLIED WARRANTY

105. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

106. At all times relevant to this action, Merck manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, and/or sold its Zostavax vaccine for use in preventing shingles.

107. Merck knew of the intended use of its Zostavax vaccine at the time Merck marketed, sold, and distributed its product for use by Plaintiff's physicians and healthcare providers, and impliedly warranted the product to be of merchantable quality and safe and fit for its intended use.

108. Merck impliedly represented and warranted to the medical community, the regulatory agencies, and consumers, including Plaintiff, her physicians, and her healthcare providers, that Zostavax vaccine was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

109. Merck's representations and implied warranties were false, misleading, and inaccurate because its product was defective, and not of merchantable quality.

110. At the time Merck's product was promoted, marketed, distributed, and/or sold by

Merck, Merck knew of the use for which it was intended and impliedly warranted its product to be of merchantable quality and safe and fit for such use.

111. Plaintiff, her physicians and healthcare providers, and members of the medical community reasonably relied on the superior skill and judgment of Merck, as manufacturer, developer, distributor, and seller of the Zostavax vaccine as to whether it was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the product was manufactured and sold.

112. Contrary to Merck's implied warranties, its product as used by Plaintiff was not of merchantable quality and was not safe or fit for its intended use because the product was unreasonably dangerous as described herein.

113. Merck breached its implied warranty because its product was not safely fit for its intended use and purpose.

114. Merck placed its product into the stream of commerce in a defective, unsafe, and inherently dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which it was manufactured and sold.

115. As a foreseeable, direct and proximate result of Merck's acts and omissions and Plaintiff's use of Merck's defective product, Plaintiff suffered serious physical injuries and incurred substantial medical costs and expenses to treat and care for her injuries described herein.

WHEREFORE, Plaintiff demands judgment against Merck, and requests compensatory damages for past, present, and future pain and suffering, medical costs and

expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT VI: NEGLIGENT MISREPRESENTATION

116. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

117. Merck had a duty to accurately and truthfully represent to the medical community, the FDA, and U.S. consumers, including Plaintiff, the truth regarding Merck's claims that Merck's product had been tested, and found to be safe and effective for its stated purposes. The misrepresentations made by Merck, in fact, were false and Merck was careless or negligent in ascertaining the truth of the representations at the time Merck made the misrepresentations.

118. Merck represented and marketed Zostavax as being safe and effective.

119. After Merck became aware of the risks of Zostavax, Merck failed to communicate to the Plaintiff and other members of the general public, that the administration of this vaccine increased the risk of viral infection.

120. Merck failed to exercise ordinary care in making representations concerning its product and its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce. Merck negligently and/or carelessly misrepresented and intentionally concealed the truth regarding the high risk of the product's unreasonable, dangerous and adverse side effects associated with the administration, use, and injection of the product.

121. Merck breached its duty in representing to Plaintiff, Plaintiffs' physicians and healthcare providers, and the medical community that Merck's product did not carry the risk of serious side effects such as those suffered by Plaintiff and other similarly situated patients.

122. Merck failed to warn the Plaintiff, and other consumers, of the defective condition of Zostavax, as manufactured and/or supplied by Merck.

123. Merck negligently misrepresented material facts about Zostavax in that it made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, Merck made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations.

124. The above misrepresentations were made to Plaintiff, as well as the general public.

125. Plaintiff, and Plaintiffs' healthcare providers and physicians, justifiably relied on Merck's misrepresentations.

126. Consequently, Plaintiff's use of Zostavax was to Plaintiff's detriment as Merck's negligent misrepresentations proximately caused Plaintiff's injuries and monetary losses.

127. As a foreseeable, direct, and proximate result of Merck's negligent and/or willful, intentional, and knowing misrepresentations as set forth herein, Merck knew, or had reason to know, that Merck's product had not been sufficiently tested, that the product lacked adequate, accurate, and prominent warnings, and that injection with the product created a high risk of adverse health effects, and higher than acceptable risks of harm to users, and higher than reported and represented risks of adverse side effects such as those specifically described herein.

128. As a direct and proximate consequence of Merck's negligent misrepresentations, Plaintiff sustained serious personal injuries and related losses including, but not limited to, the following:

- a. Plaintiff required and will continue to require healthcare and services;
- b. Plaintiff incurred and will continue to incur medical and related expenses; and
- c. Plaintiff suffered and will continue to suffer mental anguish, physical pain and suffering, diminished capacity for the enjoyment of life, a diminished quality of life, diminished ability to work, and other losses and damages.

WHEREFORE, Plaintiff demands judgment against Merck, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT VII: FRAUD

129. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

130. Prior to Plaintiff's use of Zostavax, Defendants fraudulently suppressed material information regarding the safety and efficacy of Zostavax, including information regarding increased adverse events, pre and post marketing. Furthermore, Defendants fraudulently concealed the safety information about the use of Zostavax. As described above, Zostavax has several well-known serious side-effects. Plaintiff believes that the fraudulent misrepresentation described herein was intentional to keep the sales volume of Zostavax strong.

131. Defendants falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, the FDA, and the public in general, that said product, Zostavax, had been tested and was found to be safe and/or effective to prevent shingles.

132. These representations were made by said Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said product, Zostavax, for use to prevent shingles, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

133. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff used Zostavax, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

134. In reliance upon said representations, Plaintiff was induced to use Zostavax, thereby sustaining severe and permanent personal injuries.

135. Said Defendants knew and were aware, or should have been aware, that Zostavax had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

136. Defendants knew or should have known that Zostavax had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

137. Defendants brought Zostavax to the market, and acted fraudulently, wantonly and maliciously to the detriment of Plaintiff.

138. At the time Defendants concealed the fact that Zostavax was not safe, Defendants were under a duty to communicate this information to Plaintiff, the FDA, the healthcare community, and the general public in such a manner that they could appreciate the risks associated with using Zostavax.

139. Defendants, at all times relevant hereto, withheld information from the FDA which they were required to report.

140. Plaintiff and Plaintiff's healthcare providers relied upon the Defendants' outrageous untruths regarding the safety of Zostavax.

141. Plaintiff and Plaintiff's healthcare providers were not provided with the necessary information by the Defendants, to provide an adequate warning to Plaintiff.

142. Zostavax was improperly marketed to the Plaintiff and Plaintiff's healthcare providers as the Defendants did not provide proper instructions about how to use the medication and did not adequately warn about Zostavax's risks.

143. As a direct and proximate result of Defendants' malicious and intentional concealment of material life-altering information from Plaintiff and Plaintiff's healthcare providers, Defendants caused or contributed to Plaintiff's injuries.

144. It is unconscionable and outrageous that Defendants would risk the lives of consumers, including Plaintiff. Despite this knowledge, the Defendants made conscious decisions not to redesign, label, warn or inform the unsuspecting consuming public about the dangers associated with the use of Zostavax. Defendants' outrageous conduct rises to the level

necessary that Plaintiff should be awarded punitive damages to deter Defendants from this type of outrageous conduct in the future and to discourage Defendants from placing profits above the safety of patients in the United States of America.

145. Defendants' fraud also acted to conceal their malfeasance which actions tolled Plaintiff's statute of limitations because only Defendants knew the true dangers associated with the use of Zostavax as described herein. Defendants did not disclose this information to the Plaintiff, Plaintiff's healthcare providers, the healthcare community and the general public. Without full knowledge of the dangers of Zostavax, Plaintiff could not evaluate whether a person who was injured by Zostavax had a valid claim.

146. Defendants widely advertised and promoted Zostavax as a safe and effective medication and/or as a safe and effective means of preventing shingles.

147. Defendants' advertisements regarding Zostavax falsely and misleadingly stated that Zostavax was safe and effective at preventing shingles, misrepresentations Defendants knew to be false, for the purpose of fraudulently inducing consumers, such as Plaintiff, to purchase such product. Plaintiff relied on these material misrepresentations when deciding to purchase and use Zostavax.

148. Defendants had a duty to disclose material information about serious side-effects to consumers such as Plaintiff.

149. Additionally, by virtue of Defendants' partial disclosures about the medication, in which Defendants touted Zostavax as a safe and effective medication, Defendants had a duty to disclose all facts about the risks associated with use of the medication, including the risks

described in this Complaint. Defendants intentionally failed to disclose this information for the purpose of inducing consumers, such as Plaintiff, to purchase Defendants' dangerous product.

150. Had Plaintiff been aware of the hazards associated with Zostavax, Plaintiff would have used a different shingles vaccine with a better safety profile or not have used the product that led proximately to Plaintiff's injuries (including in some cases death).

151. Upon information and belief, Plaintiff avers that Defendants actively and fraudulently concealed information in Defendants' exclusive possession regarding the hazards associated with Zostavax, for the purpose of preventing consumers, such as Plaintiff, from discovering these hazards.

COUNT VII: VIOLATION OF CONSUMER PROTECTION LAWS/CONSUMER FRAUD LAWS

152. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

153. Plaintiff used Zostavax and suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

154. Defendants used unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

- a. Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have;
- b. Advertising goods or services with the intent not to sell them as advertised; and,
- c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

155. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of Zostavax.

156. Defendants violated consumer protection laws of various states.

157. Defendants uniformly communicated the purported benefits of Zostavax while failing to disclose the serious and dangerous side effects related to the use of Zostavax and of the true state of Zostavax's regulatory status, its safety, its efficacy, and its usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers, such as Plaintiff, in the marketing and advertising campaign described herein.

158. Defendants' conduct in connection with Zostavax was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy and advantages of Zostavax.

159. As a result of these violations of consumer protection laws, Plaintiff has incurred and will incur; serious physical injury, pain, suffering, loss of income, loss of opportunity, loss of family and social relationships, and medical, hospital and surgical expenses and other expense related to the diagnosis and treatment thereof, for which Defendants are liable.

COUNT VIII: UNJUST ENRICHMENT

160. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

161. Merck is and at all times was the manufacturer, sellers, and/or supplier of the shingles vaccine, Zostavax.

162. Plaintiff paid for Merck's product for the purpose of preventing shingles.

163. Merck has accepted payment by Plaintiff for the purchase of their product.

164. Plaintiff has not received the safe and effective vaccine for which Plaintiff paid.

165. It would be inequitable for Merck to keep this money if Plaintiff did not in fact receive safe and effective treatment for the prevention of shingles.

WHEREFORE, Plaintiff demands judgment against Merck, and requests compensatory damages for past, present, and future pain and suffering, medical costs and expenses, lost wages; prejudgment and post-judgment interest as allowed by law, costs of suit and attorneys' fees, as allowed by law, punitive damages, and any and all such other relief as the Court deems just and proper; and further, demands a trial by jury of all issues so triable.

COUNT IX: PUNITIVE DAMAGES

166. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

167. Defendant's conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including the Plaintiffs, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public.

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

168. Plaintiff repeats, reiterates, incorporates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

169. The running of any statute of limitation has been tolled by reason of the Defendants' fraudulent conduct. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiffs and Plaintiffs' healthcare providers the true associated risks with using Zostavax.

170. As a result of the Defendants' fraudulent actions; Plaintiffs and Plaintiffs' healthcare providers were unaware, and could not reasonably have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks herein and that those risks were the direct and proximate result of the Defendants' acts and omissions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Merck, and each of them, individually, jointly and severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

- a. Compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;
- b. Restitution and disgorgement of profits;
- c. Reasonable attorneys' fees;
- d. The costs of these proceedings;
- e. All ascertainable economic damages;

- f. Punitive damages; and
- g. Such other and further relief as this Court deems just and proper.

Dated: December 17, 2018

Respectfully Submitted,

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